

First, applicants note that claim 2 is a generic linking claim. Applicants point out that claim 2 is generic to an OP/BMP renal therapeutic agent. Such generic claim may include, *inter alia*, OP-1, OP-2, OP-3, BMP2, BMP3, BMP4, BMP5, BMP6 and BMP9. Applicants respectfully direct the Examiner's attention to page 8, lines 14-16 which indicates the structural similarity between such OP/BMP agents, i.e. that they have homologous C-terminal 7 cysteine domains. Applicants contend that at a minimum, the Examiner should examine generic linking claim 2, i.e. one that recites OP/BMP renal therapeutic agent. Such would comprise Examiner's groups X to XVIII. Nevertheless, applicants hereby provisionally elect the OP-1 species for search purposes only.

Secondly, applicant notes that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction of Examiner's Group I from Examiner's Groups II to XLV be withdrawn in view of the fact that the claims of Examiner's Group I are not independent of Examiner's Group's II to XLV. Applicant maintains that the claims of Examiner's Group I and Examiner's Groups II to XLV do not define patentably distinct inventions. Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and effect." The OP/BMP agents have structural similarity in that they have homologous C-terminal 7 cysteine domains. Applicants contend that the Examiner should examine generic linking claim 2, i.e. one that recites OP/BMP renal therapeutic agent.

Additionally, applicant points out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants contend that the Examiner should examine the claims of Examiner's Groups I to XLV as such would not pose any additional burden on the Examiner. The elected Group X, characterized as relating to a method of treatment to delay the need for or reduce the frequency of dialysis by administering a particular OP/BMP renal therapeutic agent relates to the claims of Examiner's Groups I to IX in that a subject who is in acute renal failure may be undergoing dialysis. The Examiner should also examine the claims of Groups XIX to XXVII (allegedly relating to reducing inflammation) and Groups XXVIII to XXXVI (allegedly relating to inhibiting apoptosis) since such would be ways to treat the subject in acute renal failure or delay the need for dialysis. Thus, a search for treating or delaying the need for dialysis would also relate to inhibiting apoptosis or reducing inflammation.

In addition, the undersigned on behalf of applicants hereby elects with traverse the following species for search purposes only:

- (1) with respect to OP-1: the mature form;
- (2) with respect to causes of acute renal failure: pre-renal causes of acute renal failure;

- (3) with respect to pre-renal causes: decreased cardiac output;
- (4) with respect to routes of administration: intravenous.

Summary

For the reasons set forth herein, applicants respectfully request that the Examiner examine all of the pending claims, i.e. claims 1-52.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee, other than the \$200.00 fee for a two month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 18-1945.

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Respectfully submitted,

By 

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